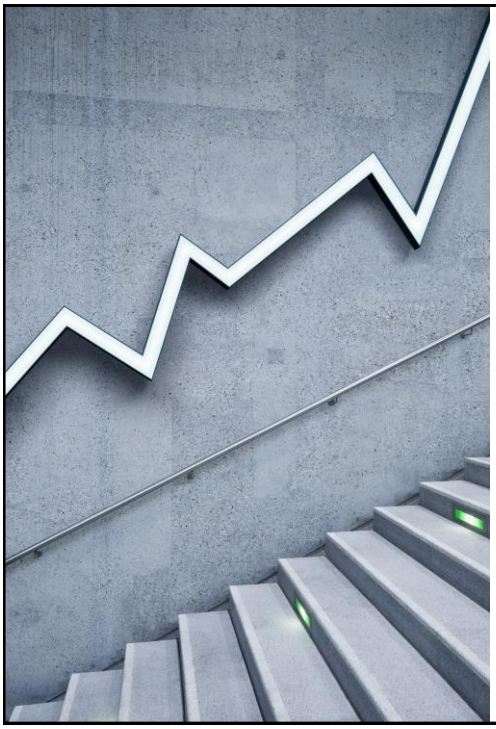

Stand Your Ground with Payers

SEAN M. WEISS, CHC,CMCO,CPMA, CEMA, CPC-P, CPC, CMIS, CMC, CMOM

DOCTORSMANAGEMENT, LLC

An aggravated assault on the English language…

- THE SUPREME COURT CHARACTERIZED THE MEDICAID STATUTE IN A 1981 OPINION, QUOTING A FEDERAL JUDGE IN NEW YORK

Ex Post Facto Laws – After the Fact; retrospectively

"Both federal and state governments are prohibited from enacting *ex post facto* laws and the Court applies the same analysis whether the law in question is a federal or a state enactment.

When these prohibitions were adopted as part of the original Constitution, many persons understood the term *ex post facto* laws to "embrace all retrospective laws, or laws governing or controlling past transactions, whether … of a civil or a criminal nature."

Every law that makes criminal an act that was innocent when done, or that inflicts a greater punishment than the law annexed to the crime when committed, is an *ex post facto* law within the prohibition of the Constitution".

Ex Post Facto Law – Continued

There are three categories of *ex post facto* laws:

- Those which punish as a crime an act previously committed, which was innocent when done;
- which make more burdensome the punishment for a crime, after its commission; or
- which deprive one charged with crime of any defense available according to law at the time when the act was committed.

SIUs, Contractors and MACs

All are bound by contractual obligations and others are bound by Statute, Regs, Acts and Laws

- Bottomline – you have to hold them accountable and not allow them to paint with broad brush strokes or to create a narrative that fits a suspected violation
- Knowing your rights and what they are bound to goes a long way to ensuring a level-playing-field
  - Contracts/Governing Documents and Policies for each payer you participate with
  - 3.3.1.1 – Medical Record Review – (Rev. 10228; Issued: 07-27-20; Effective: 08-27-20; Implementation: 08-27-20)
  - Medical Necessity – Defined by CMS, In Kaminski and in General
  - Clinical Review Judgement as defined by CMS
  - Treating Physician Rule – Not used in Social Security or Disability but often used in CMS cases
  - §1870(b) of the Act. – Overpaid Provider Not Liable Because It Was Without Fault

Contract/Governing Documents and Policies

These are crucial to any appeal/dispute with a payer.

- Providers and their leadership team must understand:
  - what is in your participation agreements
  - when they expire or if they automatically roll-over
  - what rate(s) you are reimbursed under
  - How they define “medical necessity”
  - Policies for top services billed to each payer and in the absence of an LCD/MCP, etc. how are disputes handled

3.3.1.1 – Medical Record Review

3.3.1.1 - Medical Record Review (Rev. 10228; Issued: 07-27-20; Effective: 08-27-20; Implementation: 08-27-20) This section applies to MACs, CERT, RACs, Supplemental Medical Review Contractor(s) and UPICs, as indicated.

- Clinical Review Judgment Clinical review judgment involves two steps:
  - The synthesis of all submitted medical record information (e.g., progress notes, diagnostic findings, medications, nursing notes, etc.) to create a longitudinal clinical picture of the patient; and
  - The application of this clinical picture to the review criteria is to make a reviewer determination on whether the clinical requirements in the relevant policy have been met. MAC, CERT, RAC, and UPIC clinical review staff shall use clinical review judgment when making medical record review determinations about a claim.
    - Clinical review judgment does not replace poor or inadequate medical records. Clinical review judgment by definition is not a process that MACs, CERT, RACs and UPICs can use to override, supersede or disregard a policy requirement. Policies include laws, regulations, the CMS' rulings, manual instructions, MAC policy articles attached to an LCD or listed in the Medicare Coverage Database, national coverage decisions, and local coverage determinations.

Credentials of Reviewers

The MACs, MRAC, and CERT shall ensure that medical record reviews for the purpose of making coverage determinations are performed by licensed nurses (RNs), therapists or physicians. Current LPNs may be grandfathered in and can continue to perform medical record review. The MACs, MRAC, and CERT shall not hire any new LPNs to perform medical record review. UPICs, RACs and the SMRC shall ensure that the credentials of their reviewers are consistent with the requirements in their respective SOWs.

During a medical record review, nurse and physician reviewers may call upon other health care professionals (e.g., dieticians or physician specialists) for advice. The MACs, MRAC, and CERT, shall ensure that services reviewed by other licensed health care professionals are within their scope of practice and that their MR strategy supports the need for their specialized expertise in the adjudication of particular claim type (i.e., speech therapy claim, physical therapy). RACs and the SMRC shall follow guidance related to calling upon other healthcare professionals as outlined in their respective SOWs.

RACs shall ensure that a licensed medical professional will perform medical record reviews for the purpose of determining medical necessity, using their clinical review judgment to evaluate medical record documentation. Certified coders will perform coding determinations. CERT and MACs are encouraged to make coding determinations by using certified coders. UPICs have the discretion to make coding determinations using certified coders.

Credential Files

The MACs, MRAC, CERT, RACs, and UPICs shall maintain a credentials file for each reviewer (including consultants, contract staff, subcontractors, and temporary staff) who performs medical record reviews. The credentials file shall contain at least a copy of the reviewer's active professional license.

3.3.2.4 - Signature Requirements (Rev. 10228; Issued: 07-27-20; Effective: 08-27-20; Implementation: 08-27-20)

For medical review purposes, Medicare requires that services provided/ordered/certified be authenticated by the persons responsible for the care of the beneficiary in accordance with Medicare's policies. For example, if the physician's authenticated documentation corroborates the nurse's unsigned note, and the physician was the responsible party per Medicare's payment policy, medical reviewers would consider signature requirements to have been met. The method used shall be a handwritten or electronic signature. Stamped signatures are not acceptable.

NOTE: Scribes are not providers of items or services. When a scribe is used by a provider in documenting medical record entries (e.g. progress notes), CMS does not require the scribe to sign/date the documentation. The treating physician's/non-physician practitioner's (NPP's) signature on a note indicates that the physician/NPP affirms the note adequately documents the care provided. Reviewers are only required to look for the signature (and date) of the treating physician/non-physician practitioner on the note. Reviewers shall not deny claims for items or services because a scribe has not signed/dated a note.

Exceptions to Signature Requirements

EXCEPTION 1: Facsimiles of original written or electronic signatures are acceptable for the certifications of terminal illness for hospice.

EXCEPTION 2: There are some circumstances for which an order does not need to be signed. For example, orders for some clinical diagnostic tests are not required to be signed. The rules in 42 CFR 410 and Pub.100-02 chapter 15, §80.6.1 state that if the order for the clinical diagnostic test is unsigned, there must be medical documentation (e.g., a progress note) by the treating physician that he/she intended the clinical diagnostic test be performed. This documentation showing the intent that the test be performed must be authenticated by the author via a handwritten or electronic signature.

EXCEPTION 3: Other regulations and the CMS' instructions regarding conditions of payment related to signatures (such as timeliness standards for particular benefits) take precedence. For medical review purposes, if the relevant regulation, NCD, LCD and CMS manuals are silent on whether the signature needs to be legible or present and the signature is illegible/missing, the reviewer shall follow the guidelines listed below to discern the identity and credentials (e.g., MD, RN, etc.) of the signator. In cases where the relevant regulation, NCD, LCD and CMS manuals have specific signature requirements, those signature requirements take precedence.

EXCEPTION 4: CMS would permit use of a rubber stamp for signature in accordance with the Rehabilitation Act of 1973 in the case of an author with a physical disability that can provide proof to a CMS contractor of his/her inability to sign their signature due to their disability. By affixing the rubber stamp, the provider is certifying that they have reviewed the document.

NOTE: Conditions of participation (COP) are not conditions of payment

Providers should not add late signatures to the medical record, (beyond the short delay that occurs during the transcription process) but instead should make use of the signature authentication process. The signature authentication process described below should also be used for illegible signatures.

Handwritten Signatures

A handwritten signature is a mark or sign by an individual on a document signifying knowledge, approval, acceptance or obligation.

- If the signature is illegible, MACs, UPICs, SMRC, and CERT shall consider evidence in a signature log, attestation statement, or other documentation submitted to determine the identity of the author of a medical record entry.
- If the signature is missing from an order, MACs, SMRC, and CERT shall disregard the order during the review of the claim (e.g., the reviewer will proceed as if the order was not received).
- If the signature is missing from any other medical documentation (other than an order), MACs, SMRC, and CERT shall accept a signature attestation from the author of the medical record entry.

Signature Attestation

Providers will sometimes include an attestation statement in the documentation they submit. In order to be considered valid for Medicare medical review purposes, an attestation statement must be signed and dated by the author of the medical record entry and must contain sufficient information to identify the beneficiary. Should a provider choose to submit an attestation statement, they may choose to use the following statement:

"I, [print full name of the physician/practitioner] , hereby attest that the medical record entry for [date of service] accurately reflects signatures/notations that I made in my capacity as [insert provider credentials, e.g., M.D.] when I treated/diagnosed the above listed Medicare beneficiary. I do hereby attest that this information is true, accurate and complete to the best of my knowledge and I understand that any falsification, omission, or concealment of material fact may subject me to administrative, civil, or criminal liability."

Although this format is acceptable, the CMS currently neither requires nor instructs providers to use a certain form or format. A general request for signature attestation shall be considered a non-standardized follow-up question from the contractors to the providers. However, since no form for signature attestation has been approved by the Office of Management and Budget (OMB), the contractors should not give the providers any standard format on which to submit the attestation. Once the OMB has assigned an OMB Paperwork Reduction Act number to this attestation form, its use will be mandatory.

Note: The MACs and CERT shall NOT consider attestation statements where there is no associated medical record entry. Reviewers shall NOT consider attestation statements from someone other than the author of the medical record entry in question (even in cases where two individuals are in the same group, one should not sign for the other in medical record entries or attestation statements). Reviewers shall consider all attestations that meet the above requirements regardless of the date the attestation was created, except in those cases where the regulations or policy indicate that a signature must be in place prior to a given event or a given date. For example, if a policy states the physician must sign the plan of care before therapy begins, an attestation can be used to clarify the identity associated with an illegible signature. However, such attestation cannot be used to "backdate" the plan of care.

AMA Definition of Risk – When Clinical and Non-Clinical Review Deployed by Payer

"Definitions of risk are based upon the usual behavior and thought processes of a physician or other qualified health care professional in the same specialty (This is why we request the credentials for the physician reviewer in this case). For the purposes of medical decision making, level of risk is based upon consequences of the problem(s) addressed at the encounter when appropriately treated. Risk also includes medical decision making related to the need to initiate or forego further testing, treatment and/or hospitalization."

Medical Necessity

"Medically Necessary" or "Medical Necessity" shall mean health care services that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are: a) in accordance with **generally accepted standards of medical practice**; b) clinically appropriate, in terms of type, frequency, extent, site and duration, and considered effective for the patient's illness, injury or disease; and c) not primarily for the convenience of the patient, physician or other health care provider, **and not more costly than an alternative service or sequence of services** at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "generally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community or otherwise consistent with the standards set forth in policy issues involving clinical judgment.

Understanding How to Defend "Medical Necessity"

Unless the contrary is specified, the term "Medical Necessity" must refer to what is medically necessary for a particular patient, and hence entails an individual assessment rather than a general determination of what works in the ordinary case.

- Second Circuit Court of Appeals, cited in Kaminski, Defining Medical Necessity, http://www.cga.ct.gov/2007/rpt/2007-r-0055.htm

Medicare's View of "Medical Necessity"

In the Medicare program, "Medical Necessity" is defined under Title XVIII of the Social Security Act, Section 1862 (a) (1) (a): "Notwithstanding any other provision of this title, no payment may be made under part A or part B for any expenses incurred for items or services which, except for items and services described in a succeeding subparagraph, are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."

The above is a legal doctrine by which evidence-based clinical standards are used to determine whether a treatment or procedure is reasonable, necessary and/or appropriate.

How Do We Defend Medical Necessity

Documentation within the Medical Record:

1. **Does "Medical Necessity" exist or likely exists, but the issue is lacking documentation in the medical record?**
   - Physicians have a responsibility to provide sufficient documentation that paints a clear picture of each and encounter
   - Determining whether the procedures in question are truly clinically necessary or if the issue is documentation related is critical to the defense of the investigation
   - Make sure that all relevant medical records have been retrieved and reviewed. This means office notes, hospital notes, nursing home, rehabilitation, etc.
   - Do LCDs or NCDs exist to provide documentation requirements
   - If the allegations are that documentation is inaccurate, have we generated clinical rebuttals to further clarify the need for services and state the physician's opinion clearly

Clear and Binding Medical Necessity Standard

- The Medicare statute requires that any "rule" requirement, or other statement of policy (other than a material coverage decision) that establishes or changes a substantive legal standard must be promulgated by regulation. 42 U.S.C § 1395hh.
  - Has CMS promulgated a standard for determining whether a service is reasonable and necessary?
  - Courts FROM TIME TO TIME give deference to the determination of the "Treating physician" (United States v. Prabhu, 442 F. Supp 2d 1008 (D. Nev 2006) – The Treating Physician Rule was removed from SSA Regulations Effective March 27, 2017
- Clarity of Medical Necessity issues affect whether a claim is "False" and whether the requisite "knowledge" exists.
  - "Claims are not 'false' under the FCA when reasonable persons can disagree regarding whether the service was properly billed to the Government." *Prabhu*
  - "a Defendant does not 'knowingly' submit a 'false' claim when his conduct is consistent with a reasonable interpretation of ambiguous regulatory guidance." *Prabhu*

Treating Physician Rule

Treating Physicians -- The first section of the Medicare statute is the prohibition "Nothing in this title shall be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided."

- From this, one could conclude that the beneficiary's physician should decide what services are medically necessary for the beneficiary, and a substantial line of authority in the Social Security disability benefits area holds that the treating physician's opinion is entitled to special weight and is binding upon the Secretary when not contradicted by substantial evidence.
- Some courts have applied the rationale of the "treating physician" rule in Medicare cases, and have rejected the Secretary's assertion that the treating physician rule should not be applied to Medicare determinations.

Treating Physician Rule Cont'd

In *Holland vs. Sullivan*, the court concluded:

- Though the considerations bearing on the weight to be accorded a treating physician's opinion are not necessarily identical in the disability and Medicare context, we would expect the Secretary to place significant reliance on the informed opinion of a treating physician and either to apply the treating physician rule, with its component of "some extra weight" to be accorded that opinion, [even if contradicted by substantial evidence], or to supply a reasoned basis, in conformity with statutory purposes, for declining to do so.

Judgement Error

"If the overpayment is the result of the insurance company changing its judgment after paying the claim -- determining the service was outside the scope of the insured's coverage plan, for example -- providers may not be obligated to reimburse the insurance company."

Many state courts have decided insurance companies are not entitled to reimbursement if the provider made no misrepresentations to prompt the payment and had no reason to suspect the payment was in error.

However, the provider cannot keep any payment that would be considered beyond the scope of the service.

Sustained or High Error Rate

Determining When a Statistical Sampling May Be Used. Under the new guidance, a contractor "shall use statistical sampling when it has been determined that a sustained or high level of payment error exists. The use of statistical sampling may be used after documented educational intervention has failed to correct the payment error." This guidance now creates a three-tier structure:

- Extrapolation *shall* be used when a sustained or high level of payment error exists.
- Extrapolation *may* be used after documented educational intervention (such as in the Targeted Probe and Educate (TPE) program).
- It follows that extrapolation should *not* be used if there is not a sustained or high level of payment error or evidence that documented educational intervention has failed.

What is a "sustained or high level of payment error?" The PIM now specifies this can be when the sample review error rate is "greater than or equal to 50[%]." This is a significant difference from error rates Medicare auditors have previously used to justify a high error rate and may provide some relief as to the punitive effects of extrapolation.

However, the "50% or greater" test is not the only method CMS permits to determine a sustained or high level of payment error. The TPE Program differs in that it ranges from 15 – 20% billed error rate.

The PIM also states that the contractor may look to the provider's history of noncompliance for the same or similar billing issues, or a historical pattern of noncompliant billing practice.

The Medicare Appeals Process

Areas to Focus:

- Determine whether the overpayment was improper;
- Determine if you were actually paid for the claim(s);
- Current and future reimbursement risk should be determined through internal audits;
- If errors are identified take corrective action via CAP;
- Determine the cost of engaging professionals to handle the appeal process, this should be broken down by stage;
- Determine whether source information exists regarding Medicare reimbursement policy and review to see if it helps or hurts your position (e.g., regulations, National Coverage Determinations, Local Coverage Determinations, professional journals, articles, etc.); and,
- Determine whether the claims were erroneous or if potential for Fraud exists

The Medicare Appeals Process

Pitfalls to Avoid:

- Don't jump to the conclusion your issue(s) require a self-disclosure protocol. Issues can often be remedied through a corrected claims process;
- Filing an appeal based on principal rather than facts and potential outcomes. Engaging the appeals process when its more intelligent and cheaper to make a refund and avoid additional costs;
- Missing filing deadlines;
- Providing limited analysis; and,
- Failing to fix identified problems going forward.

§1870(b) of the Act

Medicare Intermediary Manual Part 3 – Claims Process – Transmittal 1829

- D. Overpaid Provider Not Liable Because It Was Without Fault (§1870(b) of the Act.).–If a provider was without fault with respect to an overpayment it received (or is deemed without fault, in the absence of evidence to the contrary, because the overpayment was discovered subsequent to the third calendar year after the year of payment) it is not liable for the overpayment; therefore, it is not responsible for refunding the amount involved. You make these determinations. This provision forms the basis for policies and instructions in §§3708, 3708.1, 3708.2, 3708.4, and 3708.6.

Sec. 1870. [42. U.S.C. 1395gg]:

"(c) There shall be no adjustment as provided in subsection (b) (nor shall there be recovery) in any case where the incorrect payment has been made (including payments under section 1814(e)) with respect to an individual who is without fault or where the adjustment (or recovery) would be made by decreasing payments to which another person who is without fault is entitled as provided in subsection (b)(4), if such adjustment (or recovery) would defeat the purposes of title II or title XVIII or would be against equity and good conscience. Adjustment or recovery of an incorrect payment (or only such part of an incorrect payment as the Secretary determines to be inconsistent with the purposes of this title) against an individual who is without fault shall be deemed to be against equity and good conscience if

- (A) the incorrect payment was made for expenses incurred for items or services for which payment may not be made under this title by reason of the provisions of paragraph (1) or (9) of section 1862(a) and
- (B) if the Secretary's determination that such payment was incorrect was made subsequent to the fifth year following the year in which notice of such payment was sent to such individual; except that the Secretary may reduce such five-year period to not less than one year if he finds such reduction is consistent with the objectives of this title."

Thank You!

Sean M. Weiss, Partner, VP & Chief Compliance Officer
DoctorsManagement, LLC
sweiss@drsmgmt.com
800-635-4040